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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,203	02/01/2002	Avi J. Ashkenazi	P3130R1C5	6062

30313 7590 06/14/2004

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/066,203	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/29/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's preliminary amendment filed on 01 February 2002 is acknowledged and entered. Following the amendment, the original claims 1-39 are canceled, and the new claims 40-52 are added.

Currently, claims 40-52 are pending and under consideration.

Formal Matters:

Priority

This application claims priority to US provisional application 60/149,396, PCT/US00/08439, PCT/US00/13358, PCT/US00/14042, and US application 10/002,796. For the following reasons, the Examiner finds that the present claims 40-52 are not supported in the manner required by 35 U.S.C. 101 and 112, first paragraph by the prior applications, thus none of present claims is entitled to the benefit of the filling date of the prior applications.

The priority documents 60/149,396, PCT/US00/08439, PCT/US00/13358 merely disclose a polynucleotide sequence of SEQ ID NO:62 encoding a polypeptide of SEQ ID NO:63, which is designated PRO7170, and they fail to provide any specific, substantial and credible utility, nor guidance or working examples to teach how to used the claimed invention. The later PCT/US00/14042, and US application 10/002,796 disclose a working example (Example 61) indicating that the PRO7170 polypeptide was tested positive as either stimulators or inhibitors of glucose or FFA uptake in skeletal muscle, which is determined as insufficient to support a specific and substantial utility for the reasons addressed under ***Objections and Rejections under 35 U.S.C. §101 and §112*** below. Therefore, the Examiner is not able to establish that any of the priority documents satisfies the utility/enablement requirement of 35 U.S.C. 101/112, first paragraph. As such, the claims of the instant application are not entitled to the benefit of the filling date of above prior applications, and the effective filing date for the instantly claimed invention is 02 February 2002, the actual filing date of the instant application.

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 40-52 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 40-52 are directed to an isolated polypeptide having an amino acid sequence of SEQ ID NO:63, % variants thereof, and a fusion protein thereof. The polypeptide is designated PRO7170.

The specification discloses a human polypeptide, PRO7170, having an amino acid sequence SEQ ID NO:63, which is encoded by a polynucleotide of SEQ ID NO:62. There is no specific biological significance directly associated with the PRO7170 disclosed in the specification. A working example of detection of polypeptides that affect glucose or FFA uptake in skeletal muscle (Example 61) is noted in the specification, in which PRO7170 polypeptide, along with several other polypeptides, were tested positive as *either stimulators or inhibitors* of glucose or FFA uptake (page 143, lines 12-14). Such cannot be used to support a specific and substantial utility for the PRO7170 because the specification does not make it clear whether the PRO7170 stimulates or inhibits glucose or FFA uptake as stimulation and inhibition are mutually exclusive, and both cannot be true. Further, even if the PRO7170 were specifically indicated to stimulate or inhibit glucose or FFA uptake in skeletal muscle, it does not constitute an assertion of a specific and substantial utility because it is still unclear whether such an activity is associated with any biological significance, what it can be used for in a "real world", and what well-established utility is associated with the activity.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-52 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility, or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Further, *even if* the specification taught how to use the PRO7170 polypeptide, enablement would not be commensurate in scope with claims 40-45, 48, 49, 51 and 52, which encompass % variants of SEQ ID NO:63 (claims 40-44, for example), and a fragment of the extracellular domain of SEQ ID NO:63 (claims 40-44, 48 and 49, for example).

The specification discloses *one* PR PRO7170 amino acid sequence with particularity. No other PRO7170 variants or fragments meeting the limitations of these claims were ever identified or particularly described. The specification does not teach how to make PRO7170 variants or fragments. Since a biological function of PRO7170 is not clear, and since one skilled in the art could not determine with a reasonable expectation of success what a biological function of PRO7170 would be, the skilled artisan would not be able to make PRO7170 variants or fragments, and test them for a biological activity. Furthermore, the specification provides no guidance as to how the skilled artisan could use an inactive PRO7170 variant or fragment, as no functional limitation associated with the PRO7170 variants or fragment in the claims. Therefore, it would require undue experimentation to practice this invention as claimed, because the skilled artisan would have no reasonable expectation of being able to make and use the PRO7170 variants or fragments for any purpose stated in the specification.

Claims 40-45, 48, 49, 51 and 52 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Claims 40-45, 48, 49, 51 and 52 encompass variant polypeptides having at least 80% sequence identity with a particular disclosed sequence, such as SEQ ID NO:63, or "an extracellular domain" of SEQ ID NO:63 (claims 40-45, parts (c) and (d), for example). The specification discloses an amino acid sequence of human PRO7170 with SEQ ID NO:63. No variants, "an extracellular domain" or other PRO7170 fragments thereof meeting the limitation of the claim were ever identified or particularly described. As so, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In the instant application, applicants have a single polypeptide with specific functions that have not been correlated to any particular structural regions. Therefore, only isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO:63, but not the full breadth of the claims (variants and fragments) meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40-45, 48 and 49 recite the "extracellular domain". However, the protein identified as PRO7170 is a soluble protein, and is not disclosed as being expressed on a cell surface. Accordingly, the limitation that the claimed protein comprises the "extracellular domain" is indefinite, as the art does not recognize soluble proteins as having such domains. Further, if the protein had an extracellular domain, the recitation of "the extracellular domain ..., lacking its associated signal sequence" (claim 40, part (d), for example) is indefinite as a signal sequence is not generally considered to be part of an extracellular domain, as signal sequences are cleaved from said domains in the process of secretion from the cell.

The remaining claims are rejected for depending from an indefinite claim.

Rejections Over Prior Art:

The following rejections under 35 U.S.C. §§ 102 and 103 are made in view of the determination that the effective filing date for the instantly claimed invention is 02 February 2002, which is the actual filing date of the instant application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Bandman et al. (WO 00/68380).

Bandman disclose a human polypeptide sequence, EXMAD-3 (SEQ ID NO:3), which is an extracellular matrix and adhesion-associated protein, and is 100% identical to SEQ ID NO:63 of the instant application (see computer printout of the search results). The referenced sequence,

therefore, anticipates claims 40-46, 48 and 50, as being a polypeptide having at least 80-99% amino acid sequence identity to SEQ ID NO:63, or comprising the amino acid sequence of SEQ ID NO:63 or of the extracellular domain of SEQ ID NO:63. With respect to the limitation of "lacking its associated signal peptide" in claims 47 and 49, the reference further teaches a nucleic acid (SEQ ID NO:28) encoding said polypeptide, and recombinant expression of said nucleic acid in transfected mammalian cells (page 32). Thus, when the nucleic acid of the prior art is expressed in the transfected cells, the resulted polypeptide would inherently lack the signal peptide. Therefore, the reference anticipates claims 47 and 49. Further, Bandman teaches a fusion protein comprising said polypeptide and a heterologous peptide such as a Flag tag or a his-tag (page 34, the last paragraph), thus, also anticipates claims 51 and 52.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
6/8/04